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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/706,128	XIE ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) *16,17 and 19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 23-26 are added. Claims 16,17,19-26 are pending.

2. Amended claims 16,17,19-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
Claims 16,17,19-22 are directed to method for inhibitor design. Compared to their original version or to new claims 23-26, directed to method for identifying an inhibitor, claims 16,17,19-22 are directed to method which has different objectives and effect. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16,17,19-22 are withdrawn from consideration as being directed to a non-elected invention, and new claims 23-26 are being addressed.

Applicant's have been fully considered and they are deemed to be persuasive-in-part. Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claims 23-26 address identifying inhibitor of an JNK3; however, it is not clear which JNK3 protein is meant. It is known that there is a plurality of JNK3 proteins (see, e.g., Davis et al (US 6,943,000); teaches that there is a plurality of JNK3 proteins known (see, e.g., col. 2, lines 18,19; col. 3, last paragraph). The instant claims 16,17,20 address particular amino acid residues but it is not clear residues of which JNK3 protein are meant. Figure 1A to which claim 16 refers does not clarify which JNK3 is depicted therein.

Response to arguments

Applicant asserts that a person skilled in the art would recognize that JNK3 refers to JNK3α. It is not clear why reference to JNK3 equals to JNK3α. For example, Davis et al, teaches in the part addressed by applicant that "JNK3" can refer to polypeptide such as the sequences shown in FIGS. 1A-5B. Looking at Fig. 4B, for example, one would find completely different residues at positions addressed in the claims compared to Figures 2C or 3C (even though sequence of Fig. 4B seems to coincide with parts of sequences on Figs 2C and 3C).

B. Claims 23, part a), claim 25, part c): in the phrase "... structure comprising ... a JNK3 binding pocket", it is not clear, does the 3D structure to be generated contains just one pocket? Which pocket? Pocket binding what type of ligand?

C. Claims 23 (part b), 25 (part d), the step "employing said three-dimensional structure" is confusing as it does not specify any positive steps involved in the process of "employing". As the claims do not specify with particularity what the method steps are, it is unclear what is intended to be done.

Response to arguments

In addressing rejection D) of claims 16,20, Applicant points at pages 20-22 as providing sufficient explanation of the method terms. Examiner respectfully disagrees. Specification variably addresses use of either all of residues of JNK3 (see, e.g., p. 20, line 5) or some "JNK3-like binding pockets" (see p. 21, lines 16,17) – what is "JNK3-like" is not clear - or a JNK3-like binding pocket (p. 20, line 13). It is not clear, thus, what is coordinates are being employed. Further, apart from reciting in general terms what are criteria for identifying inhibitors (e.g., being able to assume conformation that interacts with (what part of?) JNK3-like binding pocket (again, what is JNK3-like binding pocket, which pocket?) specification does not offer any further details addressing identification of particular ligands of the particular protein.

D. Claims 23 (part b), 25 (part d) lack antecedent basis as they address "said agonist or antagonist"; the preceding part of the claim does not address "agonist or antagonist", however.

E. Claims 23 (part c), 25 (part e): in addressing "said agonist...", should it be "said potential agonist..."?

F. Claims 23 (part d), 25 (part f): The term "ability to interact" is vague and indefinite. It is not clear how the objective of the claims, identifying an inhibitor, is achieved by determining "ability to interact": Will determining ability to, e.g., form hydrogen bonds with, e.g., N-terminal amino group, be sufficient to identify an inhibitor? Inhibitor of what?

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of coordinates of JNK3α1 protein, does not reasonably provide enablement for any other JNK3 protein.

The instant claims are directed to method of identifying inhibitor using coordinates of particular amino acid residues located at particular positions of the

protein's sequence. Specification teaches that the preferred embodiment is JNK3α1 (see p. 8, top). All working examples are directed to use of the same JNK3α1. Specification does not guide how to use the invention as claimed with other JNK3 proteins having differing amino acid content and sequence.

It is known that there is a plurality of JNK3 proteins. For example, Davis et al (US 6,943,000) teaches that there is a plurality of JNK3 proteins known (see, e.g., col. 2, lines 18,19; col. 3, last paragraph). Further, as an example, Su et al (US 6,162,613) addresses JNK3 protein having Gly residue at position 150 (see claim 9) – compare to instant claims 16, 20 requiring Asp residue at the same position 150. Thus, clearly, using coordinates of JNK3α1 addressed in the instant specification one skilled in the art will not be able to design inhibitors to any other proteins having different amino acid sequence.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to arguments

See response to traverse of rejection under 35 U.S.C. 112, second paragraph, paragraph #3A, above.

Claim Rejections - 35 USC § 103.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 6,943,000; effective filing date 10/03/1997) .

The claims are directed to method for identifying JNK3 inhibitor by generating three-dimensional structure containing coordinates of 25 amino acid residues (extended set of 45 residues is in claims 24,26), and using said structure to identify the inhibitor. Claim 25 also requires the step of producing a crystal of unphosphorylated JNK3.

Davis et al is directed to methods of identification and use of JNK3 modulators. The reference teaches that computer modeling is used to identify compounds that modulate activity of a JNK3 protein by reacting, for example with its active site. The active site of JNK3 can be identified using methods known in the art including, for example, X-ray crystallographic methods. Having determined the 3D structure of the active site of a JNK3 protein, candidate modulating compounds can be identified; the compounds identified in such search are those that have structures that match the active site structure, fit into the active site, or interact with groups defining the active site.

X-ray crystallographic methods can be used to identify the
active site of JNK3 by the location of a bound ligand such as c-Jun or ATF2.
The three-dimensional structure of the active site can be determined. This can be done using known methods, including X-ray crystallography, which can be used to determine a complete molecular structure... Geometric structure can be determined with a JNK3 protein bound to a natural (e.g., c-Jun or ATF2) or artificial ligand which may provide a more accurate active site structure determination"

Computer-based numerical modeling can be used to complete an incomplete or insufficiently accurate structure. Modeling methods can be used... Having determined the structure of the active site of a JNK3 protein, either experimentally, by modeling, or by a combination of methods, candidate modulating compounds can be identified by searching databases containing compounds along with information on their molecular structure. The compounds identified in such a search are those that have structures that match the active site structure, fit into the active site, or interact with groups defining the active site. The compounds identified by the search are potential JNK3 modulating compounds.

See col. 7. Further, the activity of thus identified ligands is tested. See col. 9. The method of Davis et al is applicable to any of known JNK3 proteins (see col. 3, bottom) or fragments thereof. JNK3 proteins of SEQ ID No. 5,8, for example, comprise residues as instantly claimed. JNK3 protein of SEQ ID No. 10 is a JNK3 fragment truncated at N-terminal.

Even though the method disclosed by Davis et al. does not specify the atomic coordinates of JNK3 according to Figure 1A, the specific limitations of atomic coordinates in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

The following excerpt is from M.P.E.P. 2106 Section VI :

> If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b).
> Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. In re Ngai, F.3d, 2004 WL 1068957 (Fed. Cir. May 13, 2004).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)
> Common situation involving nonfunctional descriptive material is a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Specific to the instant case, atomic coordinates in Figure 1A are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631